Remarks

I. Introduction

With the cancellation herein without prejudice of claims 4, 15, 16, 23, 27 and 28, claims 1-3, 5-14, 17-22, 24-26 and 29-31 are pending in the present application. In view of the foregoing amendment, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

II. Rejection of Claims 1-7, 12-23 and 26-31 Under 35 U.S.C. §103(a)

Claims 1-7, 12-23 and 26-31 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,110,384 ("Goux et al.") in view of U.S. Patent No. 6,258,027 ("Sternby et al."). Applicant respectfully submits these claims are not obvious over the combination of Goux et al. and Sternby et al., and requests that the §103(a) rejections be withdrawn.

Claims 1 and 2 relate to methods for determining the distribution volume of a blood component in the body of an organism during an extracorporeal blood treatment. In addition, claims 12 and 13 each relate to an apparatus for determining the distribution volume of a blood component in the body of an organism during an extracorporeal blood treatment. Claim 1 has been amended herein without prejudice to recite that the method includes the steps of "bringing about a change in the concentration of a blood component in the blood upstream of the dialyzer by a change in the concentration of a blood component in the dialyzing fluid upstream of the dialyzer", "measuring the change in the concentration of a blood component in the dialyzing fluid downstream of the dialyzer which can be attributed to the change in the concentration of the blood component in the blood as a result of the change in the concentration of the blood component in the dialyzing fluid upstream of the dialyzer" and "determining the distribution volume V of the blood component from the change in the concentration of the blood component in the dialyzing fluid upstream and downstream of the dialyzer." Support for these amendments can be found, for example, at page 20, line 1- page 22, line 16 of the Specification, which describe the method by which "distribution volume V of a blood component in the body of an organism can also be determined in arithmetic and evaluation unit 29 without explicitly ascertaining the change as a function of time in the concentration of the component in the blood Δcbi." Specification at page 20, lines 1-5.

Claim 2 has been amended herein without prejudice to recite that "the change as a function of time in the concentration of a blood component in the blood upstream of the dialyzer Δcbi as a result of the change in the concentration of the blood component in the dialyzing fluid upstream of the dialyzer is determined from the concentration of the blood component in the dialyzing fluid upstream and downstream of the dialyzer after the concentration of the blood component in the dialyzing fluid has been altered." Support for these amendments can be found, for example, at page 16, line 5- page 17, line 6 of the

Specification, which describe the method by which "[t]he change as a function of time in the blood-input concentration Δcbi is calculated." Specification at page 16, lines 5-6.

Claim 12 has been amended herein without prejudice to recite "a device for altering a concentration of the blood component in the dialyzing fluid in the dialyzing-fluid path upstream of the dialyzer" and "a measuring device for determining the concentration of the blood component in the dialyzing fluid in the dialyzing-fluid path downstream of the dialyzer. In addition, claim 12 has been amended herein without prejudice to recite "an arithmetic and evaluation unit which is designed in such a way that the distribution volume V of the blood component can be determined from a change in the concentration of the blood component in the dialyzing fluid downstream of the dialyzer which can be attributed to the change in the concentration of a blood component in the blood as a result of the change in the concentration of the blood component in the dialyzing fluid upstream of the dialyzer." Support for these amendments are set forth above in connection with claim 1.

Claim 13 has been amended herein without prejudice to recite "a device for altering a concentration of the blood component in the dialyzing fluid in the dialyzing-fluid path upstream of the dialyzer" and "a measuring device for determining the concentration of the blood component in the dialyzing fluid in the dialyzing-fluid path downstream of the dialyzer." In addition, claim 13 has been amended herein without prejudice to recite "an arithmetic and evaluation unit which is designed in such a way that the change as a function of time in the concentration of the blood component Δcbi in the blood upstream of the dialyzer as a result of the change in the concentration of the blood component in the dialyzing fluid upstream of the dialyzer can be determined from the concentration of the blood component in the dialyzing fluid upstream and downstream of the dialyzer after the concentration of the blood component in the dialyzing fluid has been altered." Support for these amendments are set forth above in connection with claim 2.

Goux et al. purport to disclose a method for determining a parameter - D (dialysance), K (clearance), Kt/v (clearance multiplied by treatment time and divided by the volume of distribution of urea), Cbin (concentration of sodium in a patient's bloodstream upstream of a hemodialyser) - indicative of the effectiveness of an extracorporeal blood treatment carried out using a membrane exchanger. Goux et al. state that the method includes the steps of flowing through the exchanger a treatment liquid having a concentration characteristic (Cd) and of varying the value of the characteristic (Cd) upstream of the exchanger for a time at the end of which the characteristic (Cd) is returned to a nominal value. Goux et al. also state that a plurality of values adopted by the characteristic (Cd) downstream of the exchanger in response to the upstream variation is measured and stored in memory. Goux et al. also state that the area (Sout) of a downstream perturbation region is determined, which is bounded by a baseline and a curve representing the variation of the measured values with respect to time. Furthermore, Goux et al. state that the parameter (D, K,

Kt/v, Cbin) indicative of the effectiveness of the treatment is calculated using the area (Sin) beneath the upstream curve and an area beneath a downstream curve.

Sternby et al. purports to relate to a method and apparatus for calculating a parameter of mass exchange of a solute fluid including passing the solute in a predetermined volume of the fluid on one side of a semi-permeable membrane in a dialyzer, passing an exchange fluid on the other side of the semi-permeable membrane, obtaining a concentration curve by repeatedly measuring the concentration of a solute such as urea in the mass exchange fluid, fitting an approximate curve having a logarithm comprising a substantially straight line with at least a portion of a concentration curve, determining a parameter of the approximation curve, and calculating the mass of urea in the predetermined volume of fluid by the formula $m=(Q_d.x.c_d)/P$ where m is the mass of the urea, Q_d is the flow rate of the exchange fluid, C_d is the concentration of the urea in the exchange fluid, and P is the parameter.

Applicants respectfully contend that claims 1, 2, 12 and 13 are not obvious over the combination of Goux et al. and Sternby et al. for at least the reason that the combination of Goux et al. and Sternby et al. do not disclose each and every element of claims 1, 2, 12 and 13. For instance, the combination of Goux et al. and Sternby et al. fail to disclose or even suggest the determination of the distribution volume on the basis of a change in the concentration of the blood component in the blood **as a result** of the change in the concentration of the blood component in the dialyzing fluid upstream of the dialyzer, as recited in claims 1, 2, 12 and 13.

The Final Office Action admits that "Goux et al. fail to disclose that the Kt/V measurement obtained in his method can be used to extrapolate V, the distribution volume of a substance in the patient's blood." Final Office Action at page 2. Sternby et al. state that "[s]ince the plasma water concentration of urea can be calculated as indicated above and the amount of urea at the start of the treatment is estimated according to the present invention, the distribution volume V of urea in the body can be calculated." Col. 20, lines 32-34. Thus, to the extent that Sternby et al. describes that a distribution volume of urea in the body can be calculated at all, Sternby et al. provides a method for calculating it that is completely different from the method recited by the present claims. Specifically, while the invention of the present claims is based on a deviation of the change in the concentration of the blood component on the blood side as a result of the change in the concentration of the blood component in the dialyzing fluid upstream of the dialyzer, Sterby et al. instead purports to describe a method for calculating a distribution volume of urea in the body by calculating a plasma water concentration of urea according to Equation 27 (see col. 20, lines 20-28), and estimating the amount of urea at the start of the treatment.

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532,

28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). As more fully set forth above, it is respectfully submitted that the combination of Goux et al. and Sternby et al. does not disclose, or even suggest, all of the features recited in claims 1, 2, 12 and 13.

Furthermore, with respect to dependent claims 3-7, 14-23 and 26-31, which depend from and thus include all of the features of a respective one of independent claims 1, 2, 12 and 13, it is respectfully submitted that the combination of Goux et al. and Sternby et al. fails to render these dependent claims unpatentable for at least the same reasons set forth above with respect to the patentability of claims 1, 2, 12 and 13. Consequently, Applicants respectfully maintain that claims 1-7, 12-23 and 26-31 should be deemed allowable, and the rejection of these claims should be withdrawn.

III. Allowed Subject Matter

Applicants gratefully acknowledge that claims 8-11, 24 and 25 are indicated to be allowed.

IV. Fees

Any additional fees or charges required at this time in connection with this application may be charged to Patent and Trademarks Office Deposit Account No. 11-0600.

V. Conclusion

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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